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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,899	11/20/2003	Ron L. Hale	00068.01R	4055

37485 7590 03/15/2007
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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/719,899

Applicant(s)

HALE ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 12/14/06.

Claims 1-38 have been cancelled and new claims 39-80 have been added. Accordingly claims 39-80 are pending.

Claim Objections

Claims 40, 42, 44, 52, 54, 56, 58, 60, 62, 64 and 73 are missing the one of the terms "and" or "or" before the last species in a markush type.

Claims 39 and 67 recite the limitation of "less than 5 microns", which is not disclosed in the specification. The cited limitation is disclosed in the Provisional 60/429,364, which the instant Application claims priority to. It is however required for the said limitation to be inserted into the specification before issuance into patent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,716,415; 6,716,416; 6,716,417; 6,737,042; 6,737,043; 6,740,307; 6,740,308; 6,740,309; 6,743,415; 6,759,029; 6,776,978; 6,780,399; 6,780,400; 6,783,753; 6,797,259; 6,803,031; 6,805,853; 6,805,854; 6,814,955; 6,855,310; 7,052,680; 7,052,679; 7,048,909; 7,045,119; 7,045,118; 7,033,575; 7,029,658; 7,022,312; 7,018,621 and 7,018,620.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. Here claims 39-80 are generic to all that is recited in claims of cited U.S. Patents. That is, claims of cited U.S. Patents fall entirely within the scope of claims 39-80, or in other words, claims 39-80 are anticipated by claims of cited U.S. Patents. Specifically, the compositions for delivery and the kits comprising the compositions and devices for their delivery of the instant claims are the same as compositions and kits of the cited U.S. Patents. The instant claims recite all the therapeutic agents included in the cited Patents.

Claims 39-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos (publication document Nos), 20030138382; 20030206869; 20040009128; 20040096402; 20040099266; 20040099269; 20040101481; 20040105818; 20040105819; 20040126326; 20040126327; 20040126328;

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20040126329; 20040127481; 20040127490; 20040156788; 20040156789;
20040156790; 20040156791; 20040161385; 20040167228; 20040170569;
20040170570; 20040170571; 20040170572; 20040170573; 20040171609;
20040184996; 20040184997; 20040184998; 20040184999; 20040185000;
20040185001; 20040185002; 20040185003; 20040185004; 20040185005;
20040185006; 20040185007; 20040185008; 20040186130; 20040191179;
20040191180; 20040191181; 20040191182; 20040191183; 20040191184;
20040191185; 20040202617 and 20040228807 and Application Nos 10/749,537;
10/749,539; 10/718,982; 10/749,783; 10/768,205; 10/146,516; 10/912,462; 10/146,516;
10/150,056; 10/150,267; 10/150,268; 10/150,591; 10/150,857; 10/151,596; 10/151,626;
10/152,639; 10/152,640; 10/152,652; 10/153,139; 10/153,311; 10/153,313; 10/153,831;
10/153,839; 10/154,594; 10/154,765; 10/155,097; 10/155,373; 10/155,621; 10/155,703;
10/155,705; 10/280,315; 10/302,010; 10/302,614 and 10/322,227 . Although the
conflicting claims are not identical, they are not patentably distinct from each other
because the examined claims are either anticipated by, or would have been obvious
over, the reference claims. Here claims 39-80 are generic to all that is recited in claims
of cited copending Application Nos and publication document Nos. That is, claims of
cited copending Application Nos and publication document Nos fall entirely within the
scope of claims 39-80, or in other words, claims 39-80 are anticipated by claims of cited
copending Application Nos and publication document Nos. Specifically, the
compositions for delivery and the kits comprising the compositions and devices for their
delivery of the instant claims are the same as compositions and kits of the cited

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copending Application Nos and publication document Nos. The instant claims recite all the therapeutic agents included in the cited copending Application Nos and publication document Nos.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 12/14/06, with respect to claims 1-38 have been fully considered and are persuasive. The rejection of claims under 35 USC 102 and 35 USC 103 have been withdrawn.

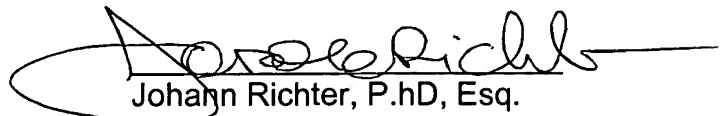
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
March 12, 2007



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Technology Center 1600